IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Art Unit: 1627
	)	
LARSEN, Michael	)	Examiner: FAY, Z.
	)	
Serial No.: 10/593,261	)	Washington, D.C.
	)	
Filed: July 11, 2007	)	April 18, 2012
	)	
For: PREVENTION OF RETINOPATHY BY INHIBITION OF THE VISUAL CYCLE	)	Docket No.: LARSEN=5
	)	
	)	Confirmation No.: 6440

PETITION FOR SUPERVISORY REVIEW

U.S. Patent and Trademark Office
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

S i r :

Pursuant 37 CFR 1.181, Applicant requests supervisory review of the rejection mailed April 2, 2012.

This petition is filed within two months of the office action complained of, and is therefore timely. No fee is required for a 1.181 petition.

1. We first direct attention to the ambiguity as to whether the action is "final" or not. In the office action summary, box "2b", "This action is non-final", is checked.

However, on page 4 of the office action, the examiner states in boldface, "THIS ACTION IS MADE FINAL". Obviously, clarification is required.

If it was the intent of the examiner to impose finality, we respectfully assert that this was improper under U.S. practice.

In response to the February 15, 2011 final rejection, applicant filed an amendment on April 14, 2011. The May 13, 2011 advisory action refused to enter the amendment on the ground that the proposed amendments "raise new issues that would require further consideration and/or search".

Consequently, on June 6, 2011, Applicant filed an RCE requesting entry of the April 14 amendment. On page 1 of the RCE, Applicant specifically remarked:

> Since the Advisory Action refused to enter the Amendment on the ground that it raised new issues, the next action cannot be made final. See MPEP 706.07(h)(VIII) and 706.07(b).

In view of the foregoing, the statement "THIS ACTION IS MADE FINAL" came as a rather unpleasant surprise.

We respectfully request that the instant rejection be plainly identified as a non-final action. Finality was premature in view of the policies set forth in the cited MPEP provisions.

2. The office action, page 2, indicates the "application's submission filed on June 6, 2011 has been entered" (the reference to "2012" on the office action summary is of course an obvious typographical error).

The June 6 submission is of course the RCE, and thus, strictly speaking, the office action should have indicated that the April 16 amendment had been entered and considered.

By that amendment, claim 59 was amended, and claims 79, 108 and 118 were cancelled. We noted at page 5 of our remarks that "the main claim (59) is now limited to fenretinide...." The cancellation of claims 79, 108 and 118 was necessitated by this amendment.

Even though the examiner had previously urged that the amendment "raised new issues", we see little evidence of new deliberation on the examiner's part. The only new text in the entire action are the last two sentences on page 4, before (the erroneous) "THIS ACTION IS MADE FINAL":

> It is also the examiner's position that if a compound is used for the treatment of proliferative diabetic retinopathy it is expected that such compound would treat non-proliferative diabetic retinopathy, considering that such disorder in encompassed by proliferative diabetic retinopathy, which is the later stages of diabetic retinopathy. Furthermore, the use of the claimed compounds in the body for any purpose is expected to reduce the risk of getting diabetic retinopathy.

We do not see how "non-proliferative" can be said to be "encompassed by proliferative", the terms seeming mutually exclusive. Moreover, this counterargument fails to address the argument made on page 6, last full paragraph of the last amendment:

> Campochiaro discloses the use of retinoic acid receptor (RAR) agonists for use in treatment of proliferative vitreoretinopathy (PVR) (abstract), which is a condition occurring after surgery or trauma (column 3 lines 49-50) and associated with retinal wound repair (column 4, line 30-32). Thus, PVR is a condition that arises after spontaneous or traumatic hole formation in the retina with subsequent detachment of the retina. PVR is independent of diabetes and distinct from diabetic retinopathy in that PVR involves proliferation of retinal pigment epithelium cells that have been transformed to have fibroblast

> characteristics whereas proliferative diabetic retinopathy involves proliferation of endothelial and angioblastic cells that form blood vessels.

See also the paragraph bridging pp. 6-7, and the first full paragraph on p. 7:

> A condition involving proliferation and detachment of the retina caused by surgery or trauma is completely different from a neuroinflammatory disease caused by diabetes. Proliferative vitreoretinopathy is an independent disease entity which is described separately from diabetic retinopathy in reference textbooks and original science communications. Thus Campochiaro et al. is viewed as irrelevant for a skilled person studying diabetic neuroinflammatory conditions.
>
> Oikawa et al. only suggests that Re 80, Am 580 and Am 80 can be used for treatment of angiogenesis-dependent diabetic retinopathy which is a sort of diabetic retinopathy characterized by the formation of new blood vessels between the retina and the vitreous body. The present invention relates to non-proliferative diabetic retinopathy and macular edema, which by definition do not involve angiogenesis (see above). Macular edema is a frequent manifestation of non-proliferative

> diabetic retinopathy and patients can develop legal blindness without having proliferative diabetic retinopathy. Hence it can be seen that clinically meaningful progression of disease does not depend upon the development of angiogenesis. Proliferative diabetic retinopathy is not generally accompanied by macular edema. However, patients suffering from proliferative diabetic retinopathy can also develop macular edema.

In addition, the examiner **completely ignores** the argument made on pp. 8-11 regarding the structural and functional differences between fenretinide and Oikawa's compounds. This is particularly striking given that the point of the amendment was to limit the claimed method to those employing fenretinide.

Consequently, Applicant respectfully asserts that the rejection is not a complete action, and should be vacated or supplemented (with period for response restarted).

Respectfully submitted,

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